Notice of Allowability	Application No.	Applicant(s)	
	09/756,398	LE ET AL.	
	Examiner	Art Unit	
	Karen A Canella	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to _____.

2. ☐ The allowed claim(s) is/are *1, 2, 4-8, 10-19, 21-23, renumbered as 1-20, respectively*.

3. ☐ The drawings filed on _____ are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date Jul 29, 2003 KAC 4/21/04
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

KAREN A. CANELLA PH.D
PRIMARY EXAMINER
Karen A. Canella

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Deidre Sanders on April 14, 2004.

The application has been amended as follows:

The amendment to the specification, filed January 26, 2004, has been deleted.

Claim 9 has been deleted.

Claim 1 has been replaced with the following:

1. An isolated nucleic acid molecule selected from the group consisting of:

a) an isolated nucleic acid molecule which hybridizes under conditions of high stringency to a nucleic acid molecule having the complementary sequence of the nucleotide sequence of SEQ ID NO: 2, wherein said isolated nucleic acid molecule, when expressed with a polynucleotide having the sequence of SEQ ID N0: 4 and a polynucleotide encoding an lgG1 immunoglobulin constant region, encodes a polypeptide which binds hTNFα, wherein said high stringency hybridization includes a wash at 68^0 C with 0.1 X SSC/0.1% SDS for 15 minutes;

b) an isolated nucleic acid molecule which hybridizes under conditions of high stringency to a nucleic acid molecule having the complementary sequence of the nucleotide sequence of SEQ ID NO: 4, wherein said isolated nucleic acid molecule, when expressed with a polynucleotide having the sequence of SEQ ID NO: 2 and a polynucleotide encoding an lgG1 immunoglobulin constant region, encodes a polypeptide which binds hTNFα, wherein said high stringency hybridization includes a wash at 68^0 C with 0.1 X SSC/0.1% SDS for 15 minutes; and

c) a complete complement of an isolated nucleic acid molecule of a) or b).

Claim 2 has been replaced with the following:

2. An isolated nucleic acid molecule selected from the group consisting of:
a) an isolated nucleic acid molecule which hybridizes under conditions of high stringency to DNA having the complementary sequence of the nucleotide sequence of SEQ ID NO: 2, wherein said isolated nucleic acid molecule, when expressed with a polynucleotide comprising the sequence of SEQ ID NO: 4 and a polynucleotide encoding an lgG1 immunoglobulin constant region, encodes a polypeptide which binds to hTNFα, wherein said high stringency hybridization includes a wash at 68^0 C with 0.1 X SSC/0.1% SDS for 15 minutes; and
b) an isolated nucleic acid molecule which hybridizes under conditions of high stringency to DNA having the complementary sequence of the nucleotide sequence of SEQ ID NO: 4, wherein said isolated nucleic acid molecule, when expressed with a polynucleotide comprising the sequence of SEQ ID NO: 2 and a polynucleotide encoding an IgG1 immunoglobulin constant region, encodes a polypeptide which binds to hTNFα.

Claim 4 has been replaced with the following:

4. An isolated nucleic acid molecule selected from the group consisting of:
a) an isolated nucleic acid molecule which, when expressed with a polynucleotide encoding a polypeptide comprising the amino acid sequence of SEQ ID NO: 5 and a polynucleotide encoding an IgG1 immunoglobulin constant region, encodes a polypeptide comprising the amino acid sequence of SEQ ID NO: 3, or a fragment thereof, which binds hTNFα;
b) an isolated nucleic acid molecule which, when expressed with a polynucleotide encoding a polypeptide comprising the amino acid sequence of SEQ ID NO: 3 and a polynucleotide encoding an IgG1 immunoglobulin constant region, encodes a polypeptide comprising the amino acid sequence of SEQ ID NO: 5, or a fragment thereof,

which binds hTNFα; and

c) a complete complement of the isolated nucleic acid molecule of a) or b).

Claim 5 has been replaced with the following:

5. An isolated nucleic acid molecule comprising a sequence selected from the group consisting of:

a) SEQ ID NO: 2,

b) the complete complementary strand of SEQ ID NO: 2;

c) DNA sequences that hybridize under conditions of high stringency to the complementary sequence of SEQ ID NO: 2 , and which, when expressed with a polynucleotide having the sequence of SEQ ID NO: 4 and a polynucleotide encoding an IgG1 immunoglobulin constant region, encode a polypeptide which binds hTNFα, wherein said high stringency hybridization includes a wash at 68^0 C with 0.1 X SSC/0.1% SDS for 15 minutes; and

d) RNA sequences transcribed from the complete sequences of a), b), or c).

Claim 6 has been replaced with the following:

6. An isolated nucleic acid molecule comprising a sequence selected from the group consisting of:

a) SEQ ID NO: 4;

b) the complete complementary strand of SEQ ID NO: 4;

c) DNA sequences that hybridize under conditions of high stringency to the complementary sequence of SEQ ID NO: 4 , and which, when expressed with a polynucleotide having the sequence of SEQ ID NO: 2 and a polynucleotide encoding an IgG1 immunoglobulin constant region, encode a polypeptide which binds hTNFα, wherein said high stringency hybridization includes a wash at 68^0 C with 0.1 X SSC/0.1% SDS for 15 minutes; and

d) RNA sequences transcribed from the complete sequences of a), b), or c).

Claim 13 has been replaced with the following:

13. An isolated nucleic acid molecule selected from the group consisting of:

a) an isolated nucleic acid molecule which hybridizes to a nucleic acid molecule having the complementary sequence of the nucleotide sequence of SEQ ID NO: 2 under wash conditions of wash solution of 68^0 C 0.1x SSC/0.1% SDS and incubation with rotation for 15 minutes at 68^0 C, wherein said isolated nucleic acid molecule, when expressed with a polynucleotide encoding SEQ ID NO: 5 and a polynucleotide encoding an lgG1 immunoglobulin constant region, encodes a polypeptide which binds hTNFα;

b) an isolated nucleic acid molecule which hybridizes to a nucleic acid molecule having the complementary sequence of the nucleotide sequence of SEQ ID NO: 4 under wash conditions of wash solution of 68^0 C 0.1x SSC/0.1% SDS and incubation with rotation for 15 minutes at 68^0 C, wherein said isolated nucleic acid molecule, when expressed with a polynucleotide encoding SEQ ID NO: 3 and a polynucleotide encoding an 1gG1 immunoglobulin constant region, encodes a polypeptide which binds hTNFα; and

c) a complete complement of an isolated nucleic acid molecule of a) or b).

Claim 14 has been replaced with the following:

14. An isolated nucleic acid molecule selected from the group consisting of:

a) an isolated DNA molecule which hybridizes to DNA having the complementary sequence of the nucleotide sequence of SEQ ID NO: 2 under wash conditions of wash solution of 68^0 C 0.1x SSC/0.1% SDS and incubation with rotation for 15 minutes at 68^0 C, wherein said isolated nucleic acid molecule, when expressed with a polynucleotide having the sequence of SEQ ID NO: 4 and a polynucleotide encoding an 1gG1 immunoglobulin constant region, encodes a polypeptide which binds hTNFα;

b) an isolated nucleic acid molecule which hybridizes to DNA having the complementary sequence of the nucleotide sequence of SEQ ID NO: 4 under wash

conditions of wash solution of 68^0 C 0.1x SSC/0.1% SDS, and incubation with rotation for 15 minutes at 68^0 C, wherein said isolated nucleic acid molecule, when expressed with a polynucleotide having the sequence of SEQ ID NO: 2 and a polynucleotide encoding an IgG1 immunoglobulin constant region, encodes a polypeptide which binds hTNFα; and

c) a complete complement of an isolated DNA molecule of a) or b).

Claim 16 has been replaced with the following:

16. An isolated nucleic acid molecule comprising a DNA sequence that hybridizes to the complementary sequence of SEQ ID NO: 2 under wash conditions including 0.1x SSC/0.1% SDS and incubation with rotation for 15 minutes at 68^0 C, wherein said molecule, when expressed with a polynucleotide having the sequence of SEQ ID NO: 4 and a polynucleotide encoding an 1gG1 immunoglobulin constant region, encodes a polypeptide which binds hTNFα, or an RNA sequence transcribed from the complete DNA sequence.

Claim 17 has been replaced with the following:

17. An isolated nucleic acid molecule comprising a DNA sequence that hybridizes to the complementary sequence of SEQ ID NO: 4 under wash conditions including 0.1x SSC/0.1% SDS and incubation with rotation for 15 minutes at 68^0 C, wherein said molecule, when expressed with a polynucleotide having the sequence of SEQ ID NO: 2 and a polynucleotide encoding an IgG1 immunoglobulin constant region, encode a polypeptide which binds hTNFα, or an RNA sequence transcribed from the complete DNA sequence.

Claim 18 has been replaced with the following:

18. An isolated DNA molecule selected from the group consisting of:

a) an isolated nucleic acid molecule which hybridizes under conditions of high stringency to a nucleic acid molecule having the complementary sequence of the

nucleotide sequence of SEQ ID NO: 2, wherein said isolated nucleic acid molecule, when expressed with a polynucleotide encoding SEQ ID NO: 5 and a polynucleotide encoding an IgG1 immunoglobulin constant region, encodes a polypeptide which binds and inhibits hTNFα, wherein said high stringency hybridization includes a wash at 68^0 C with 0.1 X SSC/0.1% SDS for 15 minutes;

b) an isolated DNA molecule which hybridizes under conditions of high stringency to a nucleic acid molecule having the complementary sequence of the nucleotide sequence of SEQ ID NO: 4, wherein said isolated nucleic acid molecule, when expressed with a polynucleotide encoding SEQ ID N0: 3 and a polynucleotide encoding an lgGl immunoglobulin constant region, encodes a polypeptide which binds and inhibits hTNFα, wherein said high stringency hybridization includes a wash at 68^0 C with 0.1 X SSC/0.1% SDS for 15 minutes; and

c) a complete complement of an isolated DNA molecule of a) or b).

Claim 19 has been replaced with the following:

19. An isolated nucleic acid molecule selected from the group consisting of:

a) an isolated nucleic acid molecule which hybridizes under conditions of high stringency to DNA having the complementary sequence of the nucleotide sequence of SEQ ID NO: 2, wherein said isolated nucleic acid molecule, when expressed with a polynucleotide encoding SEQ ID NO: 5 and a polynucleotide encoding an IgG1 immunoglobulin constant region, encodes a polypeptide which binds and inhibits hTNFα, wherein said high stringency hybridization includes a wash at 68^0 C with 0.1 X SSC/0.1% SDS for 15 minutes; and

b) an isolated nucleic acid molecule which hybridizes under conditions of high stringency to DNA having the complementary sequence of the nucleotide sequence of SEQ ID NO: 4, wherein said isolated nucleic acid molecule, when expressed with a polynucleotide encoding SEQ ID NO: 3 and a polynucleotide encoding an IgG1 immunoglobulin constant region, encodes a polypeptide which binds and inhibits

hTNFα, wherein said high stringency hybridization includes a wash at 68^0 C with 0.1 X SSC/0.1% SDS for 15 minutes.

Claim 21 has been replaced with the following:

21. An isolated nucleic acid molecule selected from the group consisting of:

a) an isolated nucleic acid molecule which, when expressed with a polynucleotide encoding a polypeptide comprising the amino acid sequence of SEQ ID NO: 5 and a polynucleotide encoding an IgG1 immunoglobulin constant region, encodes a polypeptide comprising the amino acid sequence of SEQ ID NO: 3, or a fragment thereof, which binds and inhibits hTNFα;

b) an isolated nucleic acid molecule which, when expressed with a polynucleotide encoding a polypeptide comprising the amino acid sequence of SEQ ID N0: 3 and a polynucleotide encoding an 1gG1 immunoglobulin constant region, encodes a polypeptide comprising the amino acid sequence of SEQ ID NO: 5, or a fragment thereof, which binds and inhibits hTNFα; and

c) a complete complement of the isolated nucleic acid molecule of a) or b).

Claim 22 has been replaced with the following:

22. An isolated nucleic acid molecule comprising a sequence selected from the group consisting of:

a) SEQ ID NO: 2;

b) the complete complementary strand of SEQ ID NO: 2;

c) DNA sequences that hybridize under conditions of high stringency to the complementary sequence of SEQ ID NO: 2, and which, when expressed with a polynucleotide encoding SEQ ID N0: 5 and a polynucleotide encoding an IgG1 immunoglobulin constant region, encode a polypeptide which binds and inhibits hTNFα, wherein said high stringency hybridization includes a wash at 68^0 C with 0.1 X SSC/0.1% SDS for 15 minutes; and

d) RNA sequences transcribed from the complete sequences of a), b) or c).

Claim 23 has been replaced with the following:

23. An isolated nucleic acid molecule comprising a sequence selected from the group consisting of:

a) SEQ ID NO: 4;

b) the complete complementary strand of SEQ ID NO: 4;

c) DNA sequences that hybridize under conditions of high stringency to the complementary sequence of SEQ ID N0: 4, and which, when expressed with a polynucleotide encoding SEQ ID NO: 3 and a polynucleotide encoding an lgG1 immunoglobulin constant region, encode a polypeptide which binds and inhibits hTNFα, wherein said high stringency hybridization includes a wash at 68^0 C with 0.1 X SSC/0.1% SDS for 15 minutes; and

d) RNA sequences transcribed from the complete sequences of a), b) or c).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571)272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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04/14/04

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